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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,966	05/16/2005	Manfred Auer	DC/4-32652A	2583

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EXAMINER	
WESSENDORF, TERESA D	
ART UNIT	**PAPER NUMBER**
1639	
MAIL DATE	**DELIVERY MODE**
09/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,966	AUER ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1,2,4,5 and 11-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 6-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, claims 3 and 6-10 in the reply filed on 8/29/2007 is acknowledged. Likewise, applicants' election of the following species: reactive group recited in claim 3(a) is the carbonyl group of a tripeptide: the label residue recited in claim 3(b) is LABEL 1; and the affinity tagging group recited in claim 3(c) is AFF1 (see example 8 in TABLE 1, page 22 of the specification and on page 4) is acknowledged.

Claims 1-2, 4-5, 11-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/29/2007.

Status of Claims

Claims 1-17 are pending

Claims 1-2, 4-5 and 11-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions.

Claims 3 and 6-10 are under examination.

Specification

Applicants are reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts ***for compounds or compositions***, the general nature of the compound or composition should be given as well as its use, *e.g.*, "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class.

Complete revision of the content of the abstract is required on a separate sheet.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical, grammatical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 10 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153

USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 6-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The claimed compound wherein the components are described in terms of words is indefinite and confusing. It is not clear as to the compound/component that is present in the compound and attachment of the discrete parts with one another. This seems to go against the conventional wisdom in the art of claiming a compound by its formula or structure. Cf. with all of the compounds in the Examples in the specification. It is suggested that applicants provide at least the generic formula of the compound as recited in the specification at e.g., page 35, line 5. (Claim 3).

2. It is not clear as to how a label is detected by "physical means" i.e., what is included or precluded by the term

"means". The optional limitation of the spacer and linker residues are unclear as to when the compounds are considered to include or preclude a spacer and linker residues. A compound structure should contain definite components such as to distinguish it from other compounds.

3. Claim 6 is indefinite for lack of antecedent basis for the target protein being bound to the reactive group. This broadens the base claim 1 drawn only to a compound not a fusion compound. It is further unclear as to the "reaction of the reactive group" with the functional group of the target protein or peptide to result in said fusion or complex. It is also indefinite as to what constitutes the peptide of a target no distinguishing features between a protein and peptide. This rejection has similar import to claim 7 with respect to "affinity support" and claim 9 with respect to the "solid support".

4. Claim 8 is unclear as to the "***form*** of a salt" the compound exists.

5. Claim 10 provides for the use of compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely

recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3 and 6-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Leif et al (WO 01/27625).

Leif discloses at e.g., page 15, line 1 up to page 17, line 28 a compound of the formula III:

> The polymer according to the invention can be represented by Formula III:
> (RF)n-(Tag)m-(CS)p in which each left pointing broad-arrow shape represents a monomer unit; RF represents a 8 reactive

> functionality linked to a monomer unit; Tag independently at each occurrence represents an optical-label, or other-label, or separation-tag linked to a monomer unit; CS represents at least one monomer unit constituting the cleavable link to the support Shown by the circular shape at the right; broad-arrow shapes without other indication, represent spacer 12 monomer units, n is a number from 1 to 10, m is a number from 1 to 1,000 and p is a number from 1 to 25. The first monomer unit of the polymer is covalently bound to the support or to another polymer attached to the support. The number of spacer monomers is governed by cost and depends on their position in the polymer; it can reasonably range from 0 to (20 x m) + 100. Spacer monomers can be placed within groups of both tag-bearing and reactive functionality bearing monomers. From 1 to 10 types of tags can be linked to monomer units….The polymer of the invention preferably includes from 3 to 1000 monomer units 24 and more preferably has a molecular weight in the range from 1000 to 100,000 daltons. The 25 polymer of the invention, therefore, can have bound one to approximately 1,000 tags; it can be selectively cleaved from the support by enzymatic as well as other techniques that do not destroy the tags; it can be covalently bound to an analyte-binding species or an analyte; and it can be so cleaved after being bound to this analyte-binding species or analyte. The linkage of the polymer to a solid support permits monomer units to be added in a specific order, suitably by an iterative synthesis. Thus, in the case of peptides or any other type of polymer in which specific monomer sequences permit tags to have specified relative geometric position in space….

Accordingly, the specific compound of Leif having the specific definitions for each of the variables comprised in the compound formula fully meets the broad claimed compound.

Claims 3 and 6-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Bogyo et al (WO 2002/038540).

Bogyo discloses at e.g., paragraphs [0077] up to paragraph [0101] a compound of formula:

> [0077] In certain preferred embodiments, the probes of this invention comprise a core amino acid or peptide recognition domain attached to the electrophile directly or through a linker (L). The probes also preferably include a ligand, affinity site or detectable label, and, in certain preferred embodiments, include a detectable label attached to the ligand or affinity site. Thus, in such particularly preferred embodiments the probes can the formula:
> A-Ll-(aa1)i-(aa2)j-(aa3)k-(aa4)l-L2m-E (III)
> [0078] where A is a ligand, affinity tag, or detectable label, L1 is a linker, L2, when present, is a linker, aa1, aa2, aa3, and aa4, when present, are independently selected amino acids, i, j, k, 1, and m axe independently 0 or 1, E is an electrophile, and at least one of aa1, aa2, aa3, and aa4 axe present.
> See further the definitions of each of the residues in paragraphs [0079]-[0101].

Accordingly, the specific compound of Bogyo fully meets the broad claimed compound.

Claims 3 and 6-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Ault-Riche (USP 20040048311).

Ault-Riche discloses a compound at e.g.,

> [0026] For example, in one embodiment, the tags, such as polypeptide tags, are encoded by oligonucleotides that include the formula:
>
> 5'-E.sub.m-3'
>
> [0027] wherein each E encodes a sequence of amino acids to which a capture agent, such as an antibodies, binds, each such sequence of amino acids is unique in the set, and m is, independently, an integer of 2 or higher. In another embodiment, each oligonucleotide encoding the tag, such as a

polypeptide tag, further includes a common region C of the formula:

5'C-E.sub.m3'

[0028] wherein the common region is shared by each of the oligonucleotides in a set, and is of a sufficient length to serve as a unique priming site for amplifying nucleic acid molecules that include the sequence of nucleotides that includes the common region. In another embodiment, the tags, such as polypeptide tags, are encoded by oligonucleotides that include formula:

5'-D.sub.n-E.sub.m-3'

[0029] wherein each D is a unique sequence among the set of oligonucleotides and contains at least about 10 nucleotides, each E encodes a sequence of amino acids to which a capture agent binds with each such sequence of amino acids being unique in the set and each of n and m is, independently, an integer of 2 or higher. In another embodiment, m is the number of capture agents, such as antibodies, with different polypeptide specificity, and n is from about 2 up to and including 10.sup.6. In another embodiment m is the number of capture agents, such as antibodies, with different polypeptide specificity, and n is from about 2 up to and including 10.sup.6, from about 2 up to and including 10.sup.4, from about 2 up to and including 10.sup.2 or from about 2 up to and including 10.sup.3.

symbology, a chemical tag, an electronic, such RF tag, a color-coded tag or other such identifier.

[0145] As used herein, a molecule, such as capture agent, that specifically binds to a polypeptide, such as a polypeptide tagged molecule provided herein, typically has a binding affinity (K.sub.a) of at least about 10.sup.6 l/mol, 10.sup.7 l/mol, 10.sup.8 l/mol, 10.sup.9 l/mol, 10.sup.10 l/mol or greater (generally 10.sup.8 or greater) and binds generally with greater affinity (typically at least 10-fold, generally 100-fold or) than to the molecules and biological particles that are to be detected or assessed in the methods that employ the employ the capture systems. Thus, affinity refers to the strength of interaction between a capture agent and a polypeptide tag.

[0146] As used herein, specificity (or selective binding or selectively binding) with respect to binding of tags to capture agents refers to the greater affinity the tag and capture agent exhibit for each other compared to the molecules and biological particles that are to be detected by the capture systems.

[0147] As used herein, used to "bind" to a capture system means to interact with sufficient affinity to immobilize the bound moiety (such as a biogical particle or molecule) temporarily under the conditions of a particular experiment. For purposes herein, it is an interaction that permits biological particles, such as cells, or biological molecules to be retained at a locus when biological particles or molecules are contacted with the capture systems so that they no longer move by Brownian motion or other microcurrents in a composition.

[0213] Nucleotide analogs contained in a polynucleotide can be, for example, mass modified nucleotides, which allows for mass differentiation of polynucleotides; nucleotides containing a detectable label such as a fluorescent, radioactive, luminescent or chemiluminescent label, which allows for detection of a polynucleotide; or nucleotides containing a reactive group such as biotin or a thiol group, which facilitates immobilization of a polynucleotide to a solid support. A polynucleotide also can contain one or more backbone bonds that are selectively cleavable, for example, chemically, enzymatically or photolytically. For example, a polynucleotide can include one or more deoxyribonucleotides, followed by one or more ribonucleotides, which can be followed by one or more deoxyribonucleotides, such a sequence being cleavable at the ribonucleotide sequence by base hydrolysis. A polynucleotide also can contain one or more bonds that are relatively resistant to cleavage, for example, a chimeric oligonucleotide primer, which can include nucleotides linked by peptide nucleic acid bonds and at least one nucleotide at the 3' end, which is linked by a phosphodiester bond or other suitable bond, and is capable of being extended by a polymerase. Peptide nucleic acid sequences can be prepared using well known methods (see, for example, Weiler et al. Nucleic acids Res. 25: 2792-2799 (1997)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3 and 6-10(i.e., the elected species of the fluorescent and affinity tag) is rejected under 35 U.S.C. 103(a) as being unpatentable over anyone of Leif or Bogyo or Ault-Riche in view of Auer et al (USP 6207831).

Each of Leif, Bogyo and Ault-riche references is discussed above. Each of these references does not disclose a fluorescent of the structure as recited (i.e., elected). However, Auer discloses said fluorescent compounds at e.g., cols. 47 and 48. Auer further discloses in the abstract that derivatives of fluorescent dyes of formula (I) can be used in high throughput screening both, on the solid phase as well as in homogeneous solution. Accordingly, it would have been obvious to one having ordinary skill in the art to replace the fluorescent compound in compounds of Leif or Bogyo or Ault-Riche with the compounds as taught by Auer. One having ordinary skill in the art would know

that such replacement would predictably result in identifying compounds using the labeled fluorescent compounds. KSR v. Teleflex, 17 S. Ct. 1727, 82 USPQ 2d 1385 (2007). One having ordinary skill in the art would be motivated to use the fluorescent compound of Auer if a HTH screening of compounds is desired i.e., to screen a large diverse compounds e.g., library of compounds.

No claim is allowed.

Conclusion

1. Kabat et al (7220554) discloses methods for identifying inhibitors.

2. Darrow et al (6849421) disclose compounds modulating human serine protease.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is(571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571) 272-0765. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
September 10, 2007